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ACLARA BIOSCIENCES, INC.
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EXAMINER

STARSIK, JOHN S

ART UNIT PAPER NUMBER

1753

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,181

Applicant(s)

Travis Bourne

Examiner

J. STARSIAK

Group Art Unit

1753

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 25 August 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 486 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

Art Unit: 1753

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Page 7, line 9 to page 8, line 18, describe the structure illustrated in FIG 1A. First, there is no figure labeled 1A. However, it appears that FIG. 1A is the figure on the left-hand side of FIG. 1. There are several elements recited in the written description which are not labeled in FIG. 1A. These elements include: 1) reagent reservoir 102, 2) delivery channel 104, 3) detector 122, and 4) incubation channel 105. Also, portions of the written description appear to conflict with the structure illustrated in FIG. 1A. For example page 7, lines 20-22 recites " Assay channel 144 connects *buffer reservoir 118* to waste reservoir 120. However, in FIG. 1A, reservoir 118 is labeled with an E (E=Enzyme). The written description appears to have internal conflicts. For example page 8, lines 4-6 recites, "Initially, electrodes in *reagent reservoir 102* (not labeled and/or illustrated), test compound reservoir 105 and reservoir 112 are activated to provide a field,

Art Unit: 1753

which moves the *enzymes*, compound and delivery channel 104 (not labeled and/or illustrated) for incubation in incubation channel 105 (not label and/or illustrated). Page 8, line 19-page 9, line 4 describe the structure illustrated in FIG. 1B. There is no figure labeled 1B. However, it appears that FIG. 1B is the figure on the right side of FIG. 1. Page 8, lines 14-18, recite "A pattern of units 154 and half units 156 are shown, which is referred to as an 8-plex on a 96-assay format. From figure 1B it is not possible to determine the portion of the structure shown in 1B constitutes a "unit" and what portion of the structure shown in FIG.1B constitutes a half-unit , e.g. the lead line for numeral 154 simply ends at a point on the substrate. Page 8, line 20, recites, "The reagent reservoir 102b supplies the reagent to eight assay units 100b. What constitutes an assay unit? The lead line from the numeral 100b ends between two line (channels) of figure 1B. From FIG. 1B it appears that reagent reservoir 102b supplies only four assay units (not 8), e.g. there only four 100b in FIG. 1B.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for three reasons. First, claim 1 recites "a plurality of reservoirs for providing buffer, receiving waste and *as required*, providing additional reagents. This recitation in infinite since the phrase "as required" renders the claim open ended. Second, claim 1 recites

Art Unit: 1753

two *waste sources*...". In the written description of the invention these elements are not correctly characterized as "waste reservoirs". Third, claim 1 fails to recite any structural relationships between the "common reagent source", the "two waste sources", the "plurality of reservoirs" and the elements of the "assay unit" recited in the claim, i.e. "the delivery channel" and the "assay channel". Fourth, claim 1 recites, "two waste sources for each assay, each waste shared by two assay units". This recitation is both confusing and conflicts with the specification. The specification recites [page 8, line 31-page 9, line 1], " In this way for four assay units 100b, there are a total of three waste reservoirs, two reservoirs 120b for the four assay channels 114b and one waste reservoir 112b for the four delivery channels 104b." In other words while each assay unit utilizes 2 waste reservoirs, each assay does not have two waste reservoirs. Claim 2 recites, "wherein said assay unit comprises 2 assay subunits". Claim 1 recites insufficient structure of the assay unit to given meaning to "assay subunit". The term "assay subunit" is not defined/described in the written description. Claim 6 recites, wherein the device has a row of half units of two assay units along two edges of said substrate. There is insufficient structure of the assay units and the substrate in claims 1 and 5 upon which claim 6 depends to give meaning to "half-units" or "edges of the substrate". Claim 8 is rejected for the same reasons as claim 1. Claim 12 provides for the use of microfluidic device of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 12 is rejected under 35 U.S.C. 101 because the claimed

Art Unit: 1753

recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Claim 13 is indefinite for several reasons. Claim 13 recites "including *additional* steps". How can the steps of claim 13 be "additional" when no steps are recited in claim 12 upon which claim 13 depends. There is no recitation of the structural/spatial relationship between the "site of introduction" and the elements recited in claim 1. There is no frame of reference recited to give meaning to the term "downstream". In other words the term "downstream" only has meaning when fluid is flowing through the device. Claim 14 recites, "according to claim 12, wherein said agent..." . Claim 15 recites, "...according to claim 12, wherein said site of introduction...". Neither of these recitations has proper antecedent basis in claim 12. The remaining claims are rejected because they depend on one of the above claims.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art constitutes the closest prior art to the present invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak whose telephone number is (703) 491-3786. The examiner can normally be reached on Monday to Friday from 8:00 AM to 4:30 PM.

Art Unit: 1753

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

John S. Starsiak Jr.

29 October 2003

Application/Control Number: 09/648181

Page 7

Art Unit: 1753